CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

5/14/12

To: ICOC
Fr: CIRM
Re: Consideration of regulatory amendments to the CIRM Medical and Ethical Standards

Action for ICOC Consideration:

Amended regulatory language (Attachment 1) so CIRM may proceed with rulemaking under the Administrative Procedure Act.

Background:

On 4/16/12, the Scientific and Medical Accountability Standards Working convened to consider amendments to CIRM's Medical and Ethical Standards Regulations. The Standards Working Group had the benefit of public participation during the deliberations and advanced comments on specific amendments. Amendments were proposed for two sections of the regulations:

1) § 100060: SCRO Committee Membership and Function:

   - Amend existing language to provide greater flexibility for stem cell research oversight committee operations by striking restriction on remuneration of non-scientist public member.

2) § 100070: SCRO Committee Review and Notification:

   - The current regulation requires the stem cell research oversight committee to be notified of in vitro research involving the use of individually identifiable cells and tissue. The proposed amendment would allow a designated official to be notified in lieu of a SCRO committee for in vitro research involving identifiable cells and tissue. In vitro research involving the use of individually identifiable cells and tissue must also be reviewed and approved by an institutional review board (IRB). A designated institutional official is defined as a person *designated by the chancellor, chief executive officer or person with plenary authority*.

SWG Sense of the Committee:

It was the sense of the SWG that the ICOC should consider the following new revisions as described in Attachment 1.

Attachment 1: Proposed Amendments to CIRM MES Regulations Sections 100060 & 100070 Based on SWG Deliberations April 6, 2012

§ 100060. SCRO Committee Membership and Function.

(a) A SCRO committee shall be comprised of persons with expertise in, including but not limited to, developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical issues in stem cell research. A SCRO committee shall include at least one non-scientist member of the public who is not employed by, or ~~appointed to, or remunerated by the relevant research institution and who is not~~ part of the immediate family of a person who is affiliated with the institution. In addition, a SCRO committee shall include at least one patient advocate.

§ 100070. SCRO Committee Review and Notification.

(c) CIRM-funded human subjects research, as defined by Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173 with the aim to create, from sources other than human gametes, blastocysts or embryos, or use a covered stem cell line may not commence without written notification of the SCRO committee. A statement from the designated institutional official (section 100040(b)(1)) may be provided in lieu of SCRO committee notification. The institutional official shall submit documentation of any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review. Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with section (e). The designated SCRO committee may require the investigator to:

(1) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(2) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Bioethics Committee (IBC), or other mandated review.

(3) Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.